Paper No. 50

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PETER SHORTRIDGE, KELLY SHEA DOUGHERTY
HEATHER DICKHUDT and KATE LEAVITT

Appeal No. 2004-0329
Application No. 09/251,953

HEARD: MAY 6, 2004

Before WILLIAM F. SMITH, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 24-66. Claims 24, 45, 60 and 64 are representative of the subject matter on appeal, and read as follows:

24. A method for preparing non-genetically modified processed grain when the potential for contamination of said grain by genetically modified seeds exists, comprising:

a) selecting a non-genetically modified seed stock for planting;

b) certifying that said non-genetically modified seed stock was planted and grown under conditions effective for harvesting a crop containing 5% or less genetically modified seeds;

c) harvesting said stock;

d) processing said crop under conditions effective for producing processed grain containing 5% or less genetically modified seeds; and

e) certifying that said crop was processed under said processing conditions.

45. A method for preventing contamination of non-genetically modified processed grain when the potential for contamination of said grain by genetically modified seeds exists, comprising;

a) harvesting a crop containing less than 5% genetically modified seeds;

b) certifying that said crop contains less than 5% genetically modified seeds;

c) processing said crop under conditions effective for producing processed grain containing less than 5% genetically modified seeds; and

d) certifying that said crop was processed under said processing conditions.

60. The method of claim 45, wherein said certifying step b) comprises:

i) inspecting identified acreage for contamination by genetically modified plants prior to planting; and

ii) inspecting said identified acreage for contamination by genetically modified plants prior to harvesting said crop.

64. The method of claim 45, wherein said certifying step d) comprises

i) inspecting for contamination by genetically modified seeds, prior to said harvesting step, one or more storage bins for said crop; and

ii) inspecting for contamination by genetically modified seeds, prior to said processing step, one or more processing plants that are to process said crop.

The examiner relies upon the following references:

Montanari et al. (Montanari) 5,478,990 Dec. 26, 1995

Poehlman, Breeding Field Crops, AVI Publishing Company, 2nd. Ed. pp. 449-458 (1979)

Lander, "Use of DNA in Identification," An excerpt of a talk given by Dr. Eric S. Lander at the Winding your way through DNA Symposium (1992)

Anonymous, ADM Advises Farmers to Separate their Genetically Modified Crops, Chicago Sports Final Edition, September 3, 1998, at page 4, zone: N (ADM)

Claims 24-30, 35-39, 42, 45-51 and 56-64 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of ADM and Poehlman. Claims 31-34 and 52-55 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of ADM and Poehlman, as further combined with Lander. Finally, claims 40, 41, 43, 44, 65 and 66 stand rejected under 35 U.S.C. § 103(a) over the combination of ADM and Poehlman, as further combined with Montanari. After careful review of the record and consideration of the issues before us, we affirm all of the rejections of record.

BACKGROUND

As stated in the specification:

> It can be seen that there is a need for [a] method [sic] of creating and preserving the identity of non-genetically modified seeds and grains. Over the past number of years, genetically

> modified and genetically engineered seeds and grains are becoming common place within the agriculture industry. The prevalence of these genetically altered products has given rise to a market for non-genetically modified seeds, grains, and processed products created therefrom.
>
> It can also be seen that there is a need for a method to ensure that the non-genetically modified seeds, grains, and processed products are not contaminated during the process of bringing these products to market. The method of creating non-genetically modified seeds, grains, and processed grain products begins prior to the planting of a crop and continues throughout the cultivation and harvest of a crop. Once harvested, the non-genetically modified crop's processing, packaging, and distribution must continue taking steps necessary to prevent contamination of the seeds and grains.

Id. at 1.

In order to verify that the crop produced is free of genetically modified organisms [GMO], that is, GMO free, the specification teaches:

> The verification step may also includes [sic] additional laboratory testing of the selected seed stock is performed [sic] to verify the seed stock is GMO free. These tests include an application susceptibility or detection test and a DNA level test. Satisfactory results from these tests would be influenced by labeling and testing protocols. For example, a two-tiered approach is one possible approach which may be used. For seeds, grains, and processed products which are labeled using language such as " . . . may contain GMO products," the DNA level test results in the 1-5% range may be acceptable. For seeds, grains, and processed products labeled as "free of GMO products," a more stringent standard of 0.01-0.1% results may be required. These more stringent standards may present a technical challenge to testing accuracy of DNA testing laboratories.

Id. at 6.

DISCUSSION

Claims 24-30, 35-39, 42, 45-51 and 56-64 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of ADM and Poehlman. We affirm this rejection.

ADM is cited for teaching the desirability of separating genetically modified crops, such as corn and soybeans. See Examiner's Answer, page 4. The rejection acknowledges that the ADM article does not disclose the steps for accomplishing that separation.

In order to make up the deficiency of the ADM article, the rejection relies on Poehlman. According to the Answer,

> Poehlman, however, discloses the method steps of selecting non-genetically modified seed for planting (page 451, col. 2, section (a), defined as using Foundation seed), certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5%, 1%, 0.1% or 0.01% or less genetically modified seed, (Page 451, col. 2, sections b and d; Examiner considers identifying and inspecting acreage for off-types to fall within the ambit of certifying seed was planted and grown), and harvesting, processing (defined as cleaning seed with screens etc.) and certifying the crop (page 451, col. 2, section f). The purity of the seed at the 5% or 1% or less level is shown by the certified seed tag (page 450, Fig. 20.2) with the row for "Other Crop Seed" and the accompanying percentage column. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of ADM by employing the steps as disclosed by Poehlman so as to keep seed pure under changing market conditions so as to maintain markets and prices.

Id. at 4

"[T]he Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (citation omitted). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000). In addition, the motivation to combine the references need not be "an express, written motivation" appearing in the prior art references, but may be found "in the nature of the problem to be solved." Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004).

The ADM article, published in the Chicago Tribune, is reproduced below.

> The global battle over genetically modified crops moved closer to U.S. farmers this week when agribusiness giant Archer Daniels Midland Co. warned suppliers to keep such crops separate from conventional ones.
>
> With harvest only days away in the Corn Belt, farmers and grain merchants heeding the warning will be forced to absorb additional storage and handling costs, industry sources said.
>
> "If you needed two bins before, now you will need four," said Kevin Aandahl, spokesman for the National Corn Growers Association.
>
> Crops genetically altered to resist pests or herbicides made their debut three years ago in the United States and their use has skyrocketed.

> An estimated 35 percent of this year's U.S. corn crop and 55 percent of soybeans—almost 5 billion bushels in total—will derive from genetically modified seeds.
>
> But consumer groups in Asia and the European Union, both major export markets, have generated a tide of protest against the use of modified crops in foods and livestock feed.
>
> ADM said in a statement this week that some customers are basing their purchases on the genetic origin of the crops.
>
> "We encourage you as our supplier to segregate non-genetically enhanced crops to preserve their identity," the statement said.
>
> ADM is a major buyer of crops, with more than 500 grain elevators and 355 crop processing plants worldwide.

Thus, the ADM article clearly recognizes the nature of the problem to be solved—the separation and the preservation of the identity of non-genetically modified crops. As noted by the rejection, however, the ADM article fails to explicitly set forth the steps that such separation should entail.

Poehlman, a textbook, discusses the certification of seeds, noting that "[c]ertified seed must be handled so as to maintain sufficient genetic identity and purity of the variety that it will be approved and certified by the certifying agency." Id. at 450, column 1. The reference notes that certification procedures vary from state to state, but states that such procedures generally involve the following steps:

a) planting approved seed;

b) planting the seed on clean ground;

c) isolating the crop in varieties that undergo cross-pollination;

d) removing off-type plants;

e) inspecting the field to check, among other things, the purity of the variety;

f) inspecting the seed to observe and supervise the harvesting, cleaning, grading, bagging, and other processing operations, wherein representative seed samples are taken from each seed lot after it has been cleaned, bagged and prepared for sale; and

g) tagging the seed to demonstrate that the seed meets the specific standards for the crop.

See id. at 451-52. Moreover, by following these practices, a purity of certified seed of 99.5% is achieved. See id. at page 450, Fig. 20.2.

The method steps of Poehlman read on the method steps of the instantly claimed invention. The only difference is that the method of Poehlman is drawn to growing certified seed that is of sufficient genetic identity and purity such that it will be approved by the certifying agency. The ADM article, as discussed above, recognizes the nature of the problem to be solved—the separation and the preservation of the identity of non-genetically modified crops. Therefore, it would have been prima facie obvious to use the text-book methods of Poehlman to solve the problem of ADM, that is, the separation and the preservation of the identity of non-genetically modified crops. We thus affirm the rejection of claims 24-30, 35-39, 42, 45-51 and 56-64 under 35 U.S.C. § 103(a) as being obvious over the combination of ADM and Poehlman.

Appellants argue with respect to the combination of ADM and Poehlman, that ADM "briefly mentions physical separation of harvested crops, but does not suggest any particular method of doing so." Appeal Brief, page 9. Appellants argue further that the combination "provide no reasonable expectation that

farmers and grain merchants would have been successful in segregating genetically modified and non-genetically modified crops." Id. Moreover, according to appellants, the discussion in Poehlman relates to seed certification laws and apply to seed ultimately intended for sowing, and as such do not apply to harvested crop. See id. (citing the Declaration of Robert H. Peterson, submitted June 12, 2002, Paper No. 24).

Appellants argue that Poehlman is a textbook about plant breeding, and the seed stocks described by that reference are the "merely the starting point" for the methods of the claimed invention. See Appeal Brief, page 7. Poehlman, according to appellants, does not discuss the problems in producing a non-genetically modified crop and preventing its contamination by crop that has been genetically modified. See id. at 7. In fact, appellants assert, genetically modified seeds did not even exist as of the 1979 publication date of Poehlman. See id. at 8.

Appellants contend, as discussed in the Peterson declaration, the seed certification methods of Poehlman are not applicable to the instantly claimed methods of preventing contamination by genetically modified seed. See id. at 10. For example, the scale of operations involved in producing a crop is "vastly larger" that that involved in producing seed stock. Appellants thus submit that Poehlman is non-analogous art, see id., and that the examiner has used hindsight reconstruction "in an attempt to make out a prima facie case of obviousness," id. at 11.

As stated above, the combination is not hindsight reconstruction. The ADM article recognizes the problem to be solved, and the ordinary artisan would have looked to the Poehlman textbook reference as providing methods of growing seed stock to preserve its genetic identity in order to solve the problem of preserving the genetic identity of crops such as grain. Moreover, the ADM article and the Poehlman reference are not non-analogous art, as both relate to preservation of crop identity, whether for the purpose of growing crops to obtain seed stock or the purpose of growing crops for other uses such as processing into food products. In addition, Poehlman provides a reasonable expectation of success by teaching that the methods taught therein may result in a purity of 99.5%.

With respect to the declaration of Robert H. Peterson, the declaration notes that the Poehlman reference "relates to seed certification as specified in seed laws such as those of California and Minnesota," and the "seed certification process discussed in Poehlman and specified in state seed laws is not applicable if the seed is not intended for sowing." Peterson declaration, ¶ 17. Mr. Peterson concludes that "[t]he subject matter [of the claims at issue] does not pertain to plant breeding or certification of seed intended for sowing," and that it "is [his] opinion that the seed certification process of Poehlman is not applicable to the activities of farmers and others involved in growing, harvesting and processing crops." Id. at ¶ 18. As noted by Mr. Peterson, the statements contained in the declaration are merely his opinion. In addition, as noted above, both Poehlman and the ADM article relate to the problem of preserving the

genetic identity of crops, whether for seed production or for food production. We also note in passing that most of the claims, such as claim 24, do not exclude the possibility of using the processed seeds as seed stock.

The fact that genetically modified seeds did not even exist as of the 1979 publication date of Poehlman is irrelevant. Poehlman provides a method of preserving the genetic identity of seeds. The ADM article provides the current problem to be solved, the separation and the preservation of the identity of non-genetically modified crops. The ordinary artisan would have looked to methods of preserving genetic identity that were well known in the art, such as those taught by Poehlman, and applied them to the problem recognized by the ADM article. Finally, the fact that the scale of operations involved in producing a crop may be larger than that involved in producing seed stock is also moot as the claims do not specify any scale, and thus read on the production of smaller crops as well as larger crops.

Appellants argue further that the visual screening methods taught by Poehlman cannot distinguish between genetically modified and non-genetically modified plants, “let alone a specific GMO contamination percentage, e.g., 5% or less, 1% or less, 0.1% or less, or 0.01% or less.” Appeal Brief, page 8. With respect to claims 25-30, 35-38, 46-51 and 56-59, appellants argue that the combination does not suggest a level of GMO contamination of 5% or less; 1% or less; 0.1% or less; or 0.01% or less; and thus the combination does not provide a reasonable expectation of success of achieving those contamination levels. See Appeal Brief, pages 12-14. In addition, appellants argue that the

combination provides no expectation of success of achieving the above contamination levels using application susceptibility test results. See id. at 15-16.

First, Poehlman teaches that simply by using the methods disclosed by that reference, that certified seed having a purity of 99.5%, and thus a contamination level less than 0.5%, can be achieved. Second, the claims do not exclude any screening method, including visual screening methods. And as noted by the specification, the certification or screening step that insures an Identified Preserve (IP) variety developed from non-genetically modified seed "can be verified using plant characteristics such as plant hybrid, maturity, flower color, and leaf shape," id. at 6, thus the specification does not exclude the use of visual inspection and screening. Third, appellants' invention is not drawn to methods of distinguishing between genetically modified and non-genetically modified plants, but to a "method of growing, harvesting, processing, packaging, and distributing non-genetically-modified seeds and grains [that] utilizes a comprehensive process which encompasses the entire food production system from farms to supermarkets." Id. at 2. Fourth, we find the teaching of Poehlman that simply by using the methods disclosed by that reference, that certified seed can having a contamination level less than 0.5% to be exemplary only, and not limiting. Moreover, the level of contamination is a result effective variable, and it would have been obvious to optimize the process of Poehlman to achieve any

desired level of GMO contamination.[1] Thus, one of ordinary skill in the art would know and understand what level of purity is desired and what methods to use to inspect and screen the crop to achieve the desired purity level.

Claims 31-34 and 52-55 stand rejected under 35 U.S.C. § 103(a) as being obvious over the above combination as further combined with Lander. This rejection is also affirmed.

The ADM article and Poehlman are relied upon as above. As acknowledged by the rejection, that combination fails to teach a certifying step using DNA testing.

Lander is cited for teaching the use of "DNA technology to distinguish among genotypes," and that "1 or 0.01% can be achieved by increasing the number of loci and/or individuals sampled." Examiner's Answer, page 6.

[1] We also point the examiner's and appellants' attention to the discussion of the Lander reference, infra, as further support and evidence that one of ordinary skill would understand that levels of GMO contamination of 5% or less; 1% or less; 0.1% or less; or 0.01% or less can be detected and achieved. In the event of further prosecution, the examiner may wish to consider the applicability of Lander to claims containing an express limitation of a GMO contamination level of 0.5% or less.

The rejection concludes:

> It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the steps as disclosed in ADM as modified by Poehlman by using DNA testing (fingerprinting) as disclosed by Lander in the certifying step e) so as to increase the purity of the seed planted so as to increase yield by not having off-types.

Id.

Appellants argue the Lander reference discloses DNA-based assays for comparing loci from two different individuals for purposes of determining if those two individuals are identical. See Appeal Brief, page 19. Appellants assert that the reference "makes only a brief mention of determining the similarities and differences among plants and makes no mention whatsoever of testing a sample of seeds for contamination," contending that as the Lander reference provides no motivation to arrive at the combination, the examiner used improper hindsight in making the combination. See id.

Appellants also argue that the teachings of Lander are not relevant to the present claims, as it deals with "fingerprinting," that is, "looking for similarities and differences between individuals at hundreds or thousands of different genes," whereas, "the present invention deals with the presence or absence of particular transgenes." Reply Brief, page 6. Finally, appellants argue that that the combination does not suggest a level of GMO contamination of 5% or less; 1% or less; 0.1% or less; or 0.01% or less, wherein the above percentages are based on DNA testing. See Appeal Brief, pages 17-19.

As noted by the rejection, Lander talks about the use of DNA in identification. The reference teaches that in using DNA identification methods, a very small handful of sites of variation are chosen, and that enough sites of variation are chosen in order to have enough markers of difference. And although, as noted by appellants, the reference is drawn primarily to the use of DNA identification methods, the reference teaches that you can perform DNA fingerprinting on plants, such as corn, so that one can prove ownership of the variety, which was not easily done before the use of DNA identification methods. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to use DNA identification techniques to ensure that the non-genetically modified seed has not been contaminated with genetically modified seed.

With respect to appellants' argument that the teachings of Lander are not relevant to the present claims, as it deals with "fingerprinting," whereas the present invention deals with the presence or absence of particular transgenes, the claims merely require "obtaining DNA test results," claim 31, and thus do not exclude the DNA fingerprinting methods of Lander. Moreover, Lander teaches that one chooses sites of variation, and one of ordinary skill would understand that the greatest site of variation would occur at the site of a possible transgene. In addition, because Lander teaches that DNA evidence, in principle, is rapidly becoming an irrefutable proof of identification, one of ordinary skill in the art would expect that GMO contamination of 5% or less; 1% or less; 0.1% or less; or 0.01% or less, wherein the above percentages are based on DNA testing, could be detected.

Finally, claims 40, 41, 43, 44, 65 and 66 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of ADM with Poehlman, as further combined with Montanari. We also affirm this rejection.

The combination of ADM with Poehlman is relied upon as above. With respect to claims 40 and 41, the rejection notes that the combination fails to define the processing step as a step of processing the crop into a food product.

Montanari is cited for teaching "the process of a harvested agricultural product into a food product." Examiner's Answer, page 7. Thus, according to the rejection,

> [i]t would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the steps of ADM as modified by Poehlman to include the step of processing into food as disclosed by Montanari [ ] since it is well known to process harvested crops into food products and soybean is a well known crop and constituent of food products.

Id.

With respect to claims 43 and 44, the rejection notes that the combination of ADM and Poehlman fail to disclose tracking lots through the use of ID numbers during processing. See Examiner's Answer, page 7. The rejection states Montanari discloses "the use of ID tags as ID numbers," concluding that "[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the steps of ADM as modified by Poehlman by adding the tags of Montanari [ ] when harvested so as [to] insure crop purity." Id.

In response, Appellants argue that Montanari is non-analogous art because it relates to animal processing practices, contending that "[t]here would

have been absolutely no motivation by one of ordinary skill in the art to look to the animal sciences art and the literature therein." See Appeal Brief, page 21. Appellants argue further that the fact that Montanari deals with food safety further demonstrates that it is non-analogous art. See Reply Brief, page 7. Appellants also contend that the combination does not provide "any teaching about the ability to certify 5% or less GMO contamination by tracking lot identification numbers." Appeal Brief, page 20.

While the preferred embodiment of Montanari is drawn to animal processing practices, the reference also discusses food processing practices in general. For example, the reference defines processing as referring "to the progress of a product from its origin to its final form, and more particularly refers to the growing, harvesting, smoking, cooking, grinding, cutting, seasoning, freezing, and/or curing of a product." Montanari, Col. 4, lines 17-22. In addition, the reference also teaches that the invention is drawn "to a method for tracking the production history of food products, and particularly meat products, to enable verification of the origin of such products and to trace back the source of problems that may arise at the consumer level of product distribution." Id. at Col. 3, lines 11-16.

Montanari is therefore pertinent to the issue of tracking and identifying food products throughout the production of that product, in order to allow for identification of problems in the production process, and also allowing for international organizations "with a process to identify the source and quality of food products transferred across international boundaries." Id. at Col. 3, lines

32-35. Moreover, by using such a tracking number, one can identify a particular lot of grain and follow it though the production process to ensure that the proper procedures, i.e., the procedure of obtaining certified seed as set forth by Poehlman, which achieves a purity level of 99.5%, were followed to prevent contamination with other grain products, such as grain produced using genetically modified seeds. Montanari is thus not non-analogous art, and the combination properly sets forth a prima facie case of obviousness, and the rejection is affirmed.

OTHER ISSUES

The panel would like to make of record a discussion paper prepared by the Canadian Grain Commission, published in December of 1998. The paper discusses the issues involved in setting up an identity preservation (IP) system for handling both large and small volume segregations of grain. See id. at 2. One of the possible uses for such a system is the segregation of crops that have genetically enhanced varieties, wherein genetically enhanced crops could be provided to customers willing or wanting to recive such varieties, and the system could also be used reassure customers that they are not inadvertently receiving a genetically enhanced variety. See id. at 10. Included within the paper is a suggestion from the Canadian Seed Growers' Association, using as its basis "[t]he pedigreed seed system [that] is a type of IP system that has been functioning well for a long time." Id. at 12.

CONCLUSION

Because the examiner has set forth a prima facie case of obviousness for the claims on appeal, the rejections of claims 24-66 under 35 U.S.C. § 103(a) are affirmed for the reasons set forth above.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith Administrative Patent Judge	)
	) BOARD OF PATENT
Eric Grimes Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

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